Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0232976	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cvfp-Walk In-Candlers	2832 Candlers Mountain Road, Lynchburg, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted for Physician's Treatment Center - Lynchburg on March 9, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview and remote record review conducted on 03/08/21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows (Note: the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D5400- 42 CFR. 493.1250 Condition-Analytic Systems.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review, tour, and interviews, the laboratory failed to report patient SARS-CoV-2 (COVID-19) negative results for seventy-three (73) of 73 days reviewed (timeframe: December 20, 2020 to March 9, 2021). Findings include: 1. In a pre-survey remote entrance interview on 03/08/21, the inspector noted that the laboratory director (LD) indicated on the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form that patient COVID-19 testing was performed utilizing Cepheid GeneXpert Xpress System. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 03/08/21 revealed

	an EUA was granted for the test method outlined above on 09/24/20 (updated on 01/27 /21). The FDA listing included the manufacturer's package insert / IFU which outlined General Instructions as: "Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities." 2. During a tour of the laboratory on 03/09/21 at approximately 2:00 PM the inspector noted three (3) Cepheid GeneXpert analyzers (Serial Numbers: 845816, 842726, 842727) in use for COVID-19 testing by Xpert Xpress SARS-CoV-2/Flu /RSV Cartridges. The inspector requested to review the test procedures, result logs, and evidence of results reporting to state agency. 3. Documentation revealed four hundred seventy (470) SARS-CoV-2 patient tests were analyzed on 73 test dates from 12/20/20 to 03/09/21: Three hundred forty-six (346) negative SARS-CoV-2 results were not reported to the state agency as required on 73 test days. The primary testing personnel stated at approximately 3:30 PM on 03/09/21: "One of our techs logs on to the Virginia Department of Health manual reporting portal and has entered the positive results. We have not reported negatives." 4. In an exit interview with the primary testing personnel, laboratory manager, and lab director on 03/09/21 at approximately 3:30 PM, the above findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on interviews, Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), tour of the laboratory, review of policies and procedures, maintenance logs, patient and quality control (QC) logs, and lack of documentation, the laboratory failed to: 1. have an approved policy on protocols to report patient SARS-CoV-2 (COVID-19) positive and negative results to the state agency during the timeframe of December 20, 2020 to the date of the inspection on March 9, 2021; 2. document function checks of relative centrifugal force (RCF) for the Unico urinalysis centrifuge (Serial Number L0704163) in calendar years 2019 and 2020 and maintenance for the Unico microscope (Serial Number 1971831) utilized for patient microscopy results in calendar year 2019; 3. document performance of negative and positive QC for SARS-CoV-2 testing on sixty-six (66) of seventy-three (73) days while reporting four hundred seventy (470) patient results from December 20, 2020 to March 9, 2021. See D5401, D5435, D5449.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on interviews, review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), policies and procedures, and interview, the laboratory failed to have a written policy on protocols to report patient SARS-CoV-2 (COVID-19) positive and negative results to the state agency during the timeframe of December 20, 2020 to the date of the inspection on March 9, 2021. Findings include: 1. In a pre-survey remote entrance interview on 03/08/21, the inspector noted that the laboratory director (LD) indicated on the submitted CMS 116 form the laboratory performed patient COVID-19 testing utilizing Cepheid GeneXpert Xpress System. 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 03/08/21 revealed an EUA was granted for the test method outlined above on 09/24 /20 (updated on 01/27/21). The FDA listing included the manufacturer's package insert / IFU which outlined General Instructions as: "Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities." 3. Review of the policies and procedures revealed no documentation of a policy for reporting patient COVID-19 results to the state agency. The inspector inquired of the reporting protocols to ensure all patient sample results were reported to the Virginia Department of Health (VDH). No policy was available for review. The primary testing personnel stated at approximately 3:30 PM on 03/09/21: "One of our techs logs on to the VDH manual reporting portal and has entered the positives. We do not report negatives and we do not have a written policy yet." 4. In an exit interview with the primary testing personnel, laboratory manager, and lab director on 03/09/21 at approximately 3:30 PM, the above findings were confirmed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: A. Based on a tour, review of procedures, maintenance logs, lack of documentation, and interviews, the laboratory failed to document function checks of relative centrifugal force (RCF) for the Unico urinalysis centrifuge in calendar years 2019 and 2020. Findings include: 1. During a tour of the laboratory on 03/09/21 at approximately 2:00 PM the inspector noted one (1) Unico centrifuge (Serial Number L0704163) in use for urine microscopy sediment specimen processing with sticker indicating RPM verified by the lab manager on 01/15/21. 2. Review of the laboratory's procedures revealed a Urine Sediment Examination protocol that stated "Centrifuge urine at 400 x g for 5 minutes. Higher centrifugation rates and longer centrifugation times may result in denigration of cellular casts". 3. Review of the

	laboratory's 2019 and 2020 maintenance documentation revealed no records of RCF or revolutions per minute (RPM) verifications for the Unico centrifuge outlined above. The inspector requested to review centrifugation function checks for the timeframe of January 2019 to December 2020. No documentation was available for review. 4. In an exit interview with the primary testing personnel, laboratory manager, and lab director on 03/09/21 at approximately 3:30 PM, the above findings were confirmed. B. Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour, review of maintenance logs, lack of documentation, and interviews, the laboratory failed to document maintenance protocols for one (1) Unico microscope utilized for direct wet prep/potassium hydroxide (KOH) and urine sediment microscopy in calendar year 2019. Findings include: 1. In a pre-survey remote entrance interview and review of CMS 116 form on 03/08/21, the inspector noted the laboratory director indicated patient direct wet prep/KOH and urine sediment examinations were performed during the twenty-four (24) months of review. 2. During a tour of the laboratory on 03/09/21 at approximately 2:00 PM the inspector noted one (1) Unico microscope (Serial Number 1971831) in use for microscopy procedures outlined above. 3. Review of the laboratory's 2019 and 2020 maintenance documentation revealed no records for microscope maintenance in 2019. The inspector inquired regarding the laboratory's protocols for microscope maintenance and function checks. The primary testing personnel stated, at approximately 3:00 PM, "Our QA (Quality Assurance) policy is to have the microscope maintenance done each year." The inspector requested to review microscope maintenance function checks performed in calendar year 2019. No records were available for review. The primary testing personnel stated, at approximately 3:05 PM: "We have a new company coming in to perform yearly maintenance checks on the microscope now. We reached out to contact our previous technician in 2019 and he never responded." 4. In an exit interview with the primary testing personnel, laboratory manager, and lab director on 03/09/21 at approximately 3:30 PM, the above findings were confirmed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interviews, review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), a tour, review of available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to document performance of negative and positive quality control (QC) for SARS-CoV-2 testing on sixty-six (66) of seventy-three (73) days while reporting four hundred seventy (470) patient results from December 20, 2020 to March 9, 2021. Findings include: 1. In a pre-survey remote entrance interview on 03/08/21, the inspector noted that the laboratory director (LD) indicated the laboratory performed patient COVID-19 testing utilizing Cepheid GeneXpert Xpress System on the laboratory's CMS 116 form. 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 03/08/21 revealed

	an EUA was granted for the test method outlined above on 09/24/20 (updated on 01/27 /21). The FDA listing included the manufacturer's package insert / IFU which outlined External Controls Instructions as: "External controls should be used in accordance with local, state, and federal accrediting organizations as applicable". 3. During a tour of the laboratory on 03/09/21 at approximately 2:00 PM the inspector noted three (3) Cepheid GeneXpert Xpress analyzers (Serial Numbers: 845816, 842726, 842727) in use for COVID-19 testing by Xpert Xpress SARS-CoV-2/Flu/RSV Cartridges. 4. Review of the available Xpert Xpress patient test logs revealed that the facility reported 470 results during the timeframe of 12/20/20 to 03/09/21. Review of the QC logs revealed positive and negative external controls were assayed on the following dates: 12/23/20, 01/07/21, 01/15/21, 01/29/21, 02/11/21, 02/26/21, and 03/08/21. The inspector requested to review additional QC records. No documentation was available for review. The inspector requested to review a LD approved Individualized Quality Control Plan (IQCP). No documentation was available for review. 5. In an exit interview with the primary testing personnel, laboratory manager, and lab director on 03/09/21 at approximately 3:30 PM, the above findings were confirmed.